K100284

Page 1 of ②

5.0 TRADITIONAL 510(K) SUMMARY

APR - 9 2010

Submitted by:

MedLogic Global, Ltd.
Western Wood Way
Langage Science Park
Plymouth, Devon, UK PL 5 BG

Contact Person:

Michael Browne
Quality and Regulatory Affairs Manager
MedLogic Global, Ltd

Date of Summary:

17th March 2010

Device Trade Name:

LiquiBand® Ultima

Product Code:

LUT 003

Common or Usual Name:

Topical Skin Adhesive

Classification Name:

Tissue Adhesive (21 CFR 878.4010)

Predicate Device(s):

LiquiBand® LB 0004 (K083531)

Device Description:

LiquiBand® Ultima is a sterile, topical tissue adhesive containing n-butyl-2-cyanoacrylate. LiquiBand® Ultima is supplied in a single patient use dual tip configuration.

Indication for Use:

LiquiBand® Ultima is indicated for the closure of topical skin incisions including laparoscopic incisions, and trauma-induced lacerations in areas of low skin tension that are simple, thoroughly cleansed, and have easily approximated edges. LiquiBand® Ultima may be used in conjunction with, but not in place of, deep dermal stitches.

Substantial Equivalence:

LiquiBand® Ultima is substantially equivalent to LiquiBand Topical Skin Adhesive (K083531) with regard to Indication For Use, formulation, technology, target population, intended application, mechanism of action and performance at achieving their intended use.

Substantial Equivalence Testing Summary:

The following comparative testing demonstrated substantially equivalent performance between LiquiBand Ultima and LiquiBand:

- Tensile strength (ASTM F2255-05, F2258-05, F2458-05)
- Set (polymerization) time
- Heat of polymerization
- Viscosity
- GC Chemical Analysis

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR - 9 2010

MedLogic Global, Ltd.
% Mr. Michael Browne
Quality and Regulatory Affairs Manager
Western Wood Way – Langage Science Park
Plymouth, Devon, PL7 5BG, United Kingdom

Re: K100284
Trade/Device Name: LiquiBand® Ultima
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: March 17, 2010
Received: March 22, 2010

Dear Mr. Browne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 INDICATIONS FOR USE STATEMENT

510(k) Number: K100284

Device Name: LiquiBand® Ultima

Model Number: LUT 003

Indications For Use: LiquiBand Ultima topical skin adhesive is intended for topical applications only, to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery and simple, thoroughly cleansed, trauma induced lacerations. LiquiBand Ultima topical skin adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

Prescription Use: **YES** (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use: **NO** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100284